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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,683	07/01/2003	Burke Barrett	001301-00349	3429

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EXAMINER	
SCHAETZLE, KENNEDY	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,683	BARRETT ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-29 and 31-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-29 and 31-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/31/06, 8/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 3-29 and 31-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,587,719. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 is merely a broader version of claim 1 in the '719 patent (the patented claim includes the additional wording "and intermittently" not found in the application claim). Once the applicant has received a patent for a species or a more specific embodiment, he is not entitled to a patent for the generic or broader invention (see *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)).

3. Claims 1, 3-29 and 31-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,609,025 in view of Kim et al. (Pat. No. 5,514,175). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim

1 is merely a broader version of claim 1 in the '025 patent. Once the applicant has received a patent for a species or a more specific embodiment, he is not entitled to a patent for the generic or broader invention (see *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)). The motivational comments made below in the rejection of other claims under Kim et al. apply here as well with respect to the '025 patent. Regarding claims drawn to supradiaphragmatic positioning, Kim et al. show that such a position can be effective in treating obesity since the applicable nerves can be accessed about the head region. Artisans of ordinary skill in the art given the teaching that nerves effective in treating obesity can be accessed in supradiaphragmatic positions, would have seen the obviousness of applying stimulation in such areas. The decision ultimately depending on the individual under treatment and the effectiveness of response to treatment.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3-29 and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (Pat. No. 5,514,175) in view of Zabara (Pat. No. 5,540,734).

Regarding claim 1 and claims of similar scope, bilateral stimulation of the patient's tenth cranial nerve (vagus) is accomplished via stimulus generator 11 and 11' as discussed in col. 6, lines 40-56 in order to control maladies such as obesity (note the sentence abridging columns 6 and 7, as well as the discussion of patient F in cols. 7 and 8). Although Kim et al. do not *directly* stimulate the right and left vagus nerves (Merriam Webster's defines the word *directly* to connote "...in immediate physical contact"), a person of ordinary skill in the art given the disclosure of Kim et al. would have seen the obviousness of directly applying the stimulus to the nerves to effect

obesity control because it is of general knowledge in the art that nerves may effectively be stimulated either indirectly through the skin with an external stimulator unit, or directly through the use of an implanted electrode and/or stimulator (i.e., a stimulated nerve is a stimulated nerve regardless of where the stimulation originated). In support, Zabara discloses that prior artisans have recognized that nerves such as the vagus can be stimulated either via implantable or external neurostimulating devices (see col. 1, lines 27-32). The motivation for such an implanted arrangement would be to make the system unobtrusive and aesthetically pleasing to the user –especially a user that might be embarrassed to wear an external treatment device in public. Furthermore, an external system must rely on the individual to remember to use it and properly position it if treatment is to be effective. An implantable unit eliminates the conscious effort a patient must exercise in order to benefit from the treatment. Finally, it is of general knowledge in the art that implantable systems may be necessary when precise stimulation of the nerve is required so as to avoid unintended stimulation. Because an implanted electrode can be located in immediate contact with the target nerve, inadvertent stimulation that may have resulted from extraneous sources can be avoided.

Regarding claim 3 and related claims, it is of general knowledge in the medical art that therapuetical times are highly dependent upon the condition of the patient under treatment, with the range of treatment times established by clinical studies and routine experimentation as often required by the FDA. The term "chronic" is also a relative term that has not been defined by the applicants with exactness or specificity. The applicants further state that chronic stimulation is preferred over acute stimulation, but not required (page 9, lines 1-7). Those of ordinary skill in the medical arts would have therefore considered the matter of treatment time to be an obvious matter of design dependent upon the particular individual under treatment.

Regarding claim 5 and related claims, while Kim et al. do not discuss the particular timing of treatment in relation to the circadian cycle, it would have been obvious to anyone of ordinary skill in the art looking to control obesity, to initiate

treatment during those periods of the day when the patient is feeling most hungry and would therefore be most likely to eat (i.e., during mealtimes).

Regarding claim 6 and related claims, note external ON button 10. The examiner took Official Notice in the prior Office Action that it was old and well known to provide a measure of patient control to fully implanted or partially implanted devices as well. As the applicants have not traversed the Official Notice, the feature is now considered admitted prior art.

Concerning claim 9 and related claims, Kim et al. disclose in col. 6, lines 40-56 that all the elements thus described may not be present in, on, or over both ears, further stating that one pulse generator may be used. This of course naturally implies that it would have been obvious to incorporate separate nerve stimulator generators. The choice to use one or two generators would have clearly been considered a matter of obvious design by those of ordinary skill in the art, with trade-offs between uniform manufacturing techniques and unit cost playing a role in the decision.

Concerning claims 12 and 18, the examiner considers any position above the diaphragm to be supra diaphragmatic.

In reference to claim 13, since the pulse current of Kim et al. is less than 6 mA, the examiner considers it to be inherently below a retching level.

Regarding the on-off duty cycle of claim 14, note col. 5, lines 38-45. The employment of such interim periods is clearly an application dependent parameter based upon treatment optimization. Given that Kim et al. refer to the use of on-off periods, those of ordinary skill in the art desiring to maximize obesity treatment effectiveness, would have seen the obviousness of utilizing such a pulse parameter to provide the most efficient and effective treatment possible.

Concerning claims 15 and 19, by definition it appears to be inherent that pulses would be applied during the on period of any duty cycle and not during the off period.

Concerning recitations of pulse width and duty cycle ratio in claims 21, 23 and 28, while Kim et al. do not elaborate on such specifics, the exact pulse parameters chosen to produce the sensation of saiety from patient-to-patient would have been considered a matter of obvious design by artisans of ordinary skill in the art. Routine

experimentation and optimization of parameters has been considered by the courts to be a matter of obvious design, lacking any unexpected results from the ranges recited. Attention is invited to page 4, lines 10-12 of the present specification.

Response to Arguments

6. Applicants' arguments filed August 9, 2006 have been fully considered but they are not persuasive.

7. The applicant' argue that modification of the Kim et al. invention would have required eliminating certain essential features such as providing a portable and unobtrusive auricular stimulator. It is argued that such modifications would have rendered the prior art unsatisfactory for its intended purpose by changing its principle of operation.

8. The examiner responds that any modification of Kim et al. to provide for direct stimulation of the vagus nerve as opposed to indirect stimulation would not have changed the principle of operation. An implanted unit is clearly portable, lightweight, and unobtrusive (i.e., inconspicuous) as it must be for patient acceptance, comfort and well-being. Providing for direct stimulation of the patient's tenth cranial nerve (vagus) via an implanted system rather than indirect stimulation does not render the Kim et al. reference unsatisfactory for its intended purpose of combating obesity. One would reasonably expect an implanted system that stimulates the vagus nerve to work equally well in treating medical, psychiatric or neurological disorders such as obesity, as compared to an external system that indirectly stimulates the vagus nerve given the teaching by Zabara that the vagus nerve can be stimulated either directly or indirectly to treat these conditions, and Kim's disclosure that such a neural pathway is applicable to the invention. The motivation to modify the Kim et al. reference has been set forth above under paragraph 4 of the rejection. The applicants' contention that a skilled person would be disinclined to subject the patient to the discomfort of an implant procedure if the existing method and apparatus of Kim et al. was effective in externally stimulating the vagus nerve to treat obesity, is not agreed with. A patient suffering from obesity may prefer an out-of-sight implantable system to avoid the social stigma of

wearing a visible contraption while out in public, or may require such a system if their mental facilities are such that they cannot be relied upon to attach the treatment device when necessary.

Conclusion

9. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on August 11, 2006 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJS
October 6, 2006

KENNEDY SCHAETZLE
PRIMARY EXAMINER